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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/501,555

Applicant(s)

NIKLAJSSON, BO JOHAN NIKLAS

Examiner

Michael Apanius

Art Unit

3736

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 07 December 2007.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-21 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-21 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SE/US)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

DETAILED ACTION

1. The amendments to claims 1, 13, 14 and 17-20 and the amendments to the specification are acknowledged.

Claim Rejections - 35 USC § 103

2. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

3. Claims 1, 11, 15 and 18-20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Anhäuser et al. (US 5,044,372) in view of Liedtke (DE 3811564).
4. Anhäuser discloses an epicutaneous test plaster, comprising: a flexible carrier (12) including an adhesive layer (13) for removably adhesion of the epicutaneous test plaster to a skin portion; a plurality of test chambers (around 14) distributed over the adhesive layer of the carrier; a removeable cover layer (16) extending over all the test chambers and the carrier, wherein the test chambers are formed as separate chambers, each test chamber including, a support element (14) secured to the carrier and including a support layer adhered to a moisture barrier layer (column 5, line 30), a frame-shaped plastic layer (15) secured on top of and embracing the support element, and wherein the cover layer is removably secured by way of the adhesive layer of the carrier. In regards to claim 11, each support element is secured to the carrier by way of an

adhesive layer, whose one side is fixed to the carrier and whose other side is fixed to the support element. In regards to claim 15, each frame-shaped plastic layer is secured to the support element by way of an adhesive layer, whose one side is fixed to the plastic layer and whose other side is fixed to the support element.

5. However, Anhäuser does not expressly disclose that a layer of adhesive is on the outwardly directed side of the frame-shaped plastic layer or that the frame-shaped plastic layer is foam.

6. Liedtke teaches a layer of adhesive (5) on an outwardly directed side of a frame-shaped foam plastic layer (4). The adhesive layer is for attaching the plastic layer to a test area. The adhesive layer extends all the way around the perimeter of a chamber and has an opening through which an interior of the chamber is exposed.

7. Therefore, it would have been obvious to one having ordinary skill in the art at the time of invention to have used a layer of adhesive as taught by Liedtke on the outwardly directed side of the frame-shaped plastic layers of Anhäuser in order to achieve the predictable result of providing additional adhesive to further adhere the plaster to skin.

8. In addition, it would have been obvious to one having ordinary skill in the art at the time of invention to have made the frame-shaped plastic layers of Anhäuser out of foam plastic as taught by Liedtke in order to achieve the predictable result of using an alternative fluid impermeable material to prevent unintentional migration of the liquid from the test chamber.

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9. Claims 2-4, 17 and 21 are rejected under 35 U.S.C. 103(a) as being unpatentable over Anhäuser et al. (US 5,044,372) as modified by Liedtke (DE 3811564), as applied to claims 1, 11, 15 and 18-20 above, and further in view of Rüdiger et al. (US 4,887,611).
10. Anhäuser as modified by Liedtke does not expressly disclose that the cover layer is a plastic layer with blister bubbles.
11. Rüdiger teaches an upper plastic cover layer (column 3, lines 44-47) with blister bubbles (20) and a lower cover layer, which enclose test chambers. The blister bubbles have a groove (see above 19 in figure 3) in contact with a rim of the test sites. The cover layer of Rüdiger improves handling, storage and transport of the plaster (column 3, lines 39-49).
12. Therefore, it would have been obvious to one having ordinary skill in the art at the time of invention to have substituted an upper cover layer with blister bubbles and a lower cover layer as taught by Rüdiger for the cover layer of Anhäuser as modified by Liedtke in order to achieve the predictable result of enclosing the plaster for handling, storage, and transport purposes.
13. In regards to claim 3, Rüdiger discloses that the cover layer has a polypropylene layer but does not expressly disclose that the cover layer has a polyethylene layer. However, Rüdiger states that the cover layer should be coated with an inert material (column 3, lines 45-46). Rüdiger further teaches that polypropylene and polyethylene are alternative inert plastics (column 2, lines 44-51). Therefore, it would have been obvious to one having ordinary skill in the art at the time of invention to have substituted

the polypropylene on the cover layer with polyethylene because the substitution would have yielded predictable results and because Rüdiger teaches that these two materials are alternative inert plastics.

14. Claim 5 is rejected under 35 U.S.C. 103(a) as being unpatentable over Anhäuser et al. (US 5,044,372) as modified by Liedtke (DE 3811564), as applied to claims 1, 11, 15 and 18-20 above, and further in view of Quisno (US 4,450,844).

15. Even though Anhäuser states that various materials can be used (column 3, lines 26-31), including treated papers, Anhäuser as modified by Liedtke does not expressly disclose that the cover layer is a paper liner with a silicone layer that faces the test chambers.

16. Quisno teaches a paper cover liner with a silicone layer that faces test areas (column 4, lines 33-37).

17. Therefore, it would have been obvious to one having ordinary skill in the art at the time of invention to have substituted the paper liner taught by Quisno for the cover layer of Anhäuser as modified by Liedtke because the substitution would have yielded predictable results such as protecting the adhesive until use.

18. Claim 6 is rejected under 35 U.S.C. 103(a) as being unpatentable over Anhäuser et al. (US 5,044,372) as modified by Liedtke (DE 3811564), as applied to claims 1, 11, 15 and 18-20 above, and further in view of Hoffmann (US RE37,934).

19. Although Anhäuser discloses a flexible porous surgical tape, Anhäuser as modified by Liedtke does not expressly disclose a methacrylate-based adhesive layer.

20. Hoffmann teaches a methacrylate-based adhesive layer (column 7, lines 13-26) for fixing a plaster to the skin.

21. Therefore, it would have been obvious to one having ordinary skill in the art at the time of invention to have substituted the methacrylate-based adhesive as taught by Hoffmann for the adhesive of Anhäuser as modified by Liedtke to achieve the predictable result of adhering a plaster to skin.

22. Claim 7 is rejected under 35 U.S.C. 103(a) as being unpatentable over Anhäuser et al. (US 5,044,372) as modified by Liedtke (DE 3811564), as applied to claims 1, 11, 15 and 18-20 above, and further in view of Breneman (US 4,543,964).

23. Anhäuser as modified by Liedtke teaches using a cotton support element (column 5, line 29), but does not expressly disclose that the support element is cellulose-based.

24. Breneman teaches that cotton and methyl cellulose are known alternative absorbent materials for use in a test plaster (column 4, lines 15-20).

25. Therefore, it would have been obvious to one having ordinary skill in the art at the time of invention to have substituted a cellulose-based material as taught by Breneman for the cotton of Anhäuser as modified by Liedtke to achieve the predictable result of providing an absorbent material to hold a test substance.

26. Claim 8 is rejected under 35 U.S.C. 103(a) as being unpatentable over Anhäuser et al. (US 5,044,372) as modified by Liedtke (DE 3811564), as applied to claims 1, 11, 15 and 18-20 above, and further in view of van der Bend (NL 8701577).

27. Anhäuser as modified by Liedtke does not expressly disclose that the frame-shaped foam plastic layer consists of a polyethylene foam.

28. van der Bend teaches making a frame-shaped foam plastic layer out of a polyethylene foam (see translation submitted by Applicant).

29. Therefore, it would have been obvious to one having ordinary skill in the art at the time of invention to have used a polyethylene foam as taught by van der Bend in the frame-shaped foam plastic layer of Anhäuser as modified by Liedtke because it is well-known and routine in the art to substitute alternative materials to yield predictable results.

30. Claims 9, 12 and 13 are rejected under 35 U.S.C. 103(a) as being unpatentable over Anhäuser et al. (US 5,044,372) as modified by Liedtke (DE 3811564), as applied to claims 1, 11, 15 and 18-20 above, and further in view of Pluim, Jr. (US 4,472,507).

31. In regards to claim 13, the frame-shaped foam fixing layer of Anhäuser extends outside the rim portions of the support element. Anhäuser as modified by Liedtke does not expressly disclose that the support element is secured to the carrier by a flexible double-adhesive tape or that the frame-shaped foam plastic layer is secured to the support element by a flexible double-adhesive tape.

32. Pluim teaches the use of a flexible double-adhesive tape for use in adhering layers of a carrier together (column 3, lines 17-21).

33. Therefore, it would have been obvious to one having ordinary skill in the art at the time of invention to have used a flexible double-adhesive tape as taught by Pluim in the plaster of Anhäuser as modified by Liedtke to achieve the predictable result of adhering layers together.

34. Claims 10 and 14 are rejected under 35 U.S.C. 103(a) as being unpatentable over Anhäuser et al. (US 5,044,372) as modified by Liedtke (DE 3811564) and Pluim, Jr. (US 4,472,507), as applied to claims 9, 12 and 13 above, and further in view of Kurokawa et al. (US 4,158,359).

35. Anhäuser as modified by Liedtke and Pluim does not expressly disclose using a synthetic rubber-based adhesive on the double-adhesive tape.

36. Kurokawa teaches that synthetic rubber is a known pressure-sensitive adhesive that has no influence on human skin (column 5, lines 33-38).

37. Therefore, it would have been obvious to one having ordinary skill in the art at the time of invention to have used a synthetic rubber-based adhesive as taught by Kurokawa in the plaster of Anhäuser as modified by Liedtke and Pluim to achieve the predictable result of adhering layers together with no influence on human skin.

38. Claim 16 is rejected under 35 U.S.C. 103(a) as being unpatentable over Anhäuser et al. (US 5,044,372) as modified by Liedtke (DE 3811564), as applied to claims 1, 11, 15 and 18-20 above, and further in view of Kraft et al. (US 4,809,707).

39. Anhäuser as modified by Liedtke does not expressly disclose that the frame-shaped foam plastic layer is a flexible double-adhesive tape.

40. Kraft teaches a flexible double-adhesive tape (46) surrounding a support element for the purpose of affixing the support element to a patient (column 4, lines 12-14).

41. Therefore, it would have been obvious to one having ordinary skill in the art at the time of invention to have made the frame-shaped foam plastic layer of Anhäuser as modified by Liedtke out of double-adhesive tape as taught by Kraft to achieve the predictable result of affixing a support element to a patient.

Response to Arguments

42. Applicant's arguments with respect to the combination of Anhäuser and Augustine have been considered but are moot in view of the new ground(s) of rejection.

43. In regards to the teachings of Rüdiger, Applicant argues that "the improvements taught result from much more than just the dome 20 of the upper foil." Applicant concludes, "if one skilled in the art desired to obtain Rüdiger's advantages (as alleged by the Examiner), then it would be necessary to make a series of separate, awkward combinative steps that are far too involved to be considered obvious." In response, the advantages of Rüdiger are based on the use of an upper foil together with a lower foil to enclose the plaster. The addition of an upper foil with blisters and lower foil to the

plaster of Anhäuser as modified by Liedtke is a straightforward and obvious modification. A single cover layer is simply substituted with an upper and lower cover layer.

Conclusion

44. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michael Apanius whose telephone number is (571)272-5537. The examiner can normally be reached on Mon-Fri 9am-5:30pm.

45. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Max Hindenburg can be reached on (571) 272-4726. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

46. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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/Max Hindenburg/

Supervisory Patent Examiner, Art Unit 3736